TAKAHASHI ET AL. -- 09/811,367 Client/Matter: 031989-0278719

REMARKS

This Response is filed in connection with the final Office Action mailed June 2, 2005. Applicants wish to thank the Examiner for the discussion held June 28, 2005. The amendment to claim 71 and remarks herein address all rejections of record, as discussed on June 28, 2005.

Claims 1 to 39, 41 to 65, 71 and 72 are pending. Claim 65 is allowed. By this Response, claims 1 to 39, 41 to 64 and 72 have been cancelled without prejudice. Applicants maintain the right to prosecute the cancelled claims in any related application claiming the benefit of priority of the subject application. Accordingly, upon entry of the Response, claims 65 and 72 remain.

Applicants respectfully request entry of the Response because the amendment to claim 71 places this claim in better condition for allowance or for appeal. In addition, the amendment to claim 71 does not raise new issues. Accordingly, entry of this Response is respectfully requested.

I. REGARDING THE AMENDMENTS

The amendment to claim 71 is supported throughout the specification. In particular, the amendment to claim 71 to recite that the NK or T cells generates an inhibitory signal to the NK or the T cell that inhibits "NK cell- or T cell-mediated cytotoxicity," is supported, for example, at page 10, lines 20-21, which discloses that "anti-MAFA antibodies of the invention strongly inhibited cytotoxic activity of mouse NK cells and CTLs;" at page 30, lines 1-4; and at page 32, lines 1-5. Thus, as the amendment to claim 71 is supported by the specification, no new matter has been added. In addition, because the amendment to claim 71 places the claim in better condition for allowance or for appeal and does not raise new issues, entry thereof is respectfully requested.

The specification has been amended to delete reference to ATCC at pages 5 and 7. The amendment was made to address informality and, therefore, does not add new matter. In addition, because the amendment places the application in better condition for allowance or for appeal and does not raise new issues, entry thereof is respectfully requested.

II. OBJECTION TO THE DISCLOSURE

The specification stands objected to due to incomplete ATCC information.

Applicants have amended the specification at pages 5 and 7 in order to delete reference to ATCC. Accordingly, the objection to the specification is moot.

III. REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

The rejection of claims 71 and 72 under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement is respectfully traversed. The grounds for rejection are of record.

The specification enables claims 71 and 72 prior to entry of this Response. Nevertheless, solely in order to further prosecution of the subject application and without acquiescing to the propriety of the rejection, claim 71 has been amended as set forth above and claim 72 has been cancelled herein without prejudice. The rejection will therefore be addressed as it may pertain to amended claim 71.

As discussed in the record, the specification discloses antibodies that inhibit ligand binding to NK or T cell expressed MAFA. Such anti-MAFA antibodies (e.g., 7B51 and F10) can inhibit MAFA from binding to MAFA ligand on a target cell, which can generate an inhibitory signal to the NK or the T cell that inhibits NK cell- or T cell-mediated cytotoxicity (see, for example, page 7, lines 6-12; page 10, lines 20-21; and page 31, line 11, to page 32, line 5). Thus, in view of the specification, the skilled artisan would know anti-MAFA antibodies that bind to MAFA expressed on NK or T cells that inhibit ligand binding to NK or T cell expressed MAFA, and generate an inhibitory signal to the NK or T cell that inhibits NK cell- or T cell-mediated cytotoxicity.

As also discussed in the record, the specification teaches how to produce polyclonal and monoclonal antibodies, including anti-MAFA antibodies that bind to MAFA expressed on NK or T cells that inhibit ligand binding to NK or T cell expressed MAFA on a target cell, and antibodies that generate an inhibitory signal to the NK or T cell that inhibits NK cell- or T cell-mediated cytotoxicity, using routine methods known in the art at the time of the invention (see, for example, page 22, line 16 to page 23, line 12; page 26, line 24, to page 28, line 11; and page 28, line 21, to page 29, line 11, and the references cited therein). Modified antibodies (e.g., having substitutions, deletions and additions) can readily be produced, in view of the knowledge of antibody structure and function at the time of the invention. Further in this regard, methods for producing antibodies having amino acid substitutions,

TAKAHASHI ET AL. -- 09/811,367 Client/Matter: 031989-0278719

deletions and additions, mimetics, and humanized forms are disclosed in the specification, and such methods were also known in the art at the time of the invention (see, for example, page 11, line 13, to page 12, line 15; page 13, line 11, to page 15, line 11; and page 21, lines 8-21, and the references cited therein).

Furthermore, as discussed in the record the specification discloses assays for identifying anti-MAFA antibodies having the requisite activity. For example, assays for measuring cytotoxic activity of NK and CTL cells, were routine in the art at the time of the invention (see, for example, page 28, lines 12-19; page 29, line 20, to page 30, line 7, and the references cited therein).

Thus, in view of the guidance in the specification and of knowledge in the art at the time of the invention, the skilled artisan could readily produce and identify anti-MAFA antibodies that bind to MAFA expressed on NK or T cells that inhibit ligand binding to NK or T cell expressed MAFA, and that generate an inhibitory signal to the NK or T cell that inhibits NK cell- or T cell-mediated cytotoxicity, without undue experimentation. Consequently, as such anti-MAFA antibodies could be obtained without undue experimentation, claim 71, as amended, is adequately enabled. Accordingly, Applicants respectfully request that the rejection of claim 71 under 35 U.S.C. §112, first paragraph, be withdrawn.

CONCLUSION

In summary, for the reasons set forth herein, Applicants maintain that claims 65 and 71 clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 509-4065.

Please charge any additional fees, or make any credits, to Deposit Account No. 03-3975.

Respectfully submitted,

PILLSBURY WINTHROP SMAW PITTMAN LLP

ROBERT M. BEDGOOD

Reg. No. 43488

Tel. No. 858 509.4065' Fax No. 858 509.4010

Date: November 29, 2005 11682 El Camino Real Suite 200 San Diego, CA 92130-2092 (619) 234-5000

CERTIFICATION UNDER 37 C.F.R. \$\$ 1.8 and/or 1.10*

(When using Express Mail, the Express Mail label number is mandatory; Express Mail certification is optional.)

I hereby certify that, on the date shown below, this paper (along with any paper referred to a being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: November 29, 2005

PATRICIA MUNOZ

(type or print name of person certifying)

^{*} Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.